this techniques is not well established. We sought to assess the long-term effects of intrarterial infusion of BMMC in patients with CLI.
Methods: from September 2004 to December 2007 intrarterial infusion of BMMC was performed in 28 subjects with CLI (fontain grade 3 and 4, 17 men and 11 women). The mean age was 60 years. 50% of subject in the study population had ischemic defects in the Lower limb, 53.5% diabetes mellitus, 42.8% ischemic heart disease, 67.8% arterial hypertension, 21.4% thrombangitis obliterans and 50% hyperlipoproteinemia.
Results: Major amputation was performed during follow up in 2 subjects 3 months after BMMC implantation. 11 of the 14 fourteen subject with defect had healed (79%) and the Fontaine grade improved to grade 2B in 22 subjects (84.6%). In 2 patients (7.6%) resting pain remained in spite of defects healing but were well controlled with analgesics. In 2 subjects the size of the defect was reduced one year after BMMC treatment but did not heal. The mean ankle brachial index was improved with treatment (0.54 vs 0.67, p <0.0001) and the mean tpO2 was improved (14.9 vs 37.2 mmHg, p <0.0001). The overall quality of life assessed using SF-36 questionnaire was also dramatically improved after one year (p <0.0001).After 5 years of follow up 14 patients had died (50%) due to multiple cardiovascular comorbidities. 11 individual (39%) were without resting pain and in the fontain class 2B. 3 patients (10%) were asymptomatic. None of the patient in the surviving group underwent major amputation or had ischemic defect.
Conclusions: Transcatheter intra-arterial administration of BMMC is a suitable alternative for treatment of patients with critical limb ischemia. However, the midterm benefits of this method are limited by long term unfavorable outcome due to high mortality caused by cardiovascular comorbidities

TCT-162

Distal Embolization and Protective Devices: Mortality, Operating Room Time, Length of Stay, and Costs

Eric Dippel[1], Niraj Parikh[2], Ryan Egeland[3], Katrine Wallace[2]
[1]Midwest Cardiovascular Research Foundation, Davenport, IA, [2]Covidien, Mansfield, MA, [3]Covidien, Minneapolis, MN

Background: Distal embolization (DE) events are commonly reported in percutaneous atherectomy procedures. Embolic protection (EP) devices reduce these events. This study compared inpatient hospital costs and resource utilization in two non-coronary (presumed lower extremity) atherectomy patient populations: (1) a DE event group, and (2) an EP group.
Methods: All inpatient discharges for atherectomy of non-coronary vessels (ICD-9-CM procedure code 39.50) were selected from a comprehensive hospital admissions database (Premier Perspective CY2005-20 10). DE patients were identified using ICD-9-CM diagnosis codes (444.XX, 434.0, and 434.1). Patients receiving EP devices were identified using a billing data keyword search. Discharges in the DE and EP groups were propensity matched adjusting for age, gender, race and severity scores. Inpatient mortality, length of stay, operating room (OR) time, and costs were compared between the groups.
Results: After propensity matching DE and EP groups, there were n=1,497 matched pairs. The inpatient mortality rate was significantly higher in DE compared to EP (2.7% vs. 1.3%, p<0.05). Hospital stay averaged 1.4 days longer in the DE patients (p<0.05). Room and board, surgery and pharmacy costs were significantly higher for DE (p<0.05). OR time was 24 minutes longer for DE patients. Total costs were higher but not significant for the DE group ($24,326 vs. $23,594, p=0.38). As a reference, the total rate of embolic events detected in this inpatient population was 13.5 percent.
Conclusions: The use of embolic protection is strongly associated with lower inpatient mortality rates, shorter hospital stays, and shorter OR times. Cumulatively, these findings demonstrate embolic protection devices may significantly reduce consumption of hospital resources.

TCT-163

Drug eluting balloon for below the knee angioplasty- one year results from a single center DEB-BTK Registry

Grigore Popusoi[1], Angelo Cioppa[1], Eugenio Stabile[1], Luigi Salemme[1], Vittorio Ambrosini[1], Tullio Tesorio[1], Giovanni Sorropago[2], Linda Cota[1], Armando Pucciarelli[1], Giancarlo Biamino[1], Paolo Rubino[1]
[1]Montevergine clinic, Mercogliano, Avellino, [2]Montevergine clinic, Mercogliano, Avellino

Background: Recent registries and randomized trials support the role of percutaneous revascularization in patients with critical limb ischemia (CLI) and life limiting claudication (LLC) due also to infragenicular atherosclerotic disease. However, the percutaneous transluminal angioplasty (PTA) may result in high restenosis rate and target lesion revascularization.Promising results are coming from ond randomised controlled study an single center registries using drug eluting balloon (DEB) in this arterial district.
Methods: Between December 2008 and December 2010, 75 (48 males) consecutive patients underwent percutaneous revascularization of below the knee(BTK) arteries in our institution due to CLI(58[72.5%]) and LLC(17[27.5%]). Functional status was Rutheford class 3 in 4 (5%) patients, class 4 in 24(30%) patients, class 5 in 37(50%), and class 6 in 10(15%). All patients(98 lesions) were treated predilating with an undersized standard balloon and then with Pacltaxel Eluting Balloon In.Pact Amphirion (Medtronic).No limitation in number of vessels treated, lesion length were considered (mean treated length 89±25 mm). A total occlusion was the target lesion in 47% of cases. In 22 cases above the knee arteries were previously treated.Polpliteal artery was the target lesion in 17 cases, anterior tibial artery in 28 cases, posterior tibial artery in 23 cases, peroneal artery in 16 cases.
Results: Procedural success, meaning angiographic evidence of restored antegrade flow, was achieved in 70 (94%) patients. Bail-out stenting for flow limiting dissection or abrupt target vessel occlusion was needed in 7 patients(10%). Procedural complication:distal embolization 2(2.5%),access site complication 1(1.5%), intra-hospital mortality 1(1,5%).The rate of angiographic restenosis at twelve months was 24% (n=15). Only symptomatic patients were planned for a reintervention(n=9). One-year primary patency was 76%(n=52); secondary patency was 91% (n=61).
Conclusions: The outcome of this single center experience suggest that the use of drug eluting balloon for percutaneous transluminal angioplasty of below the knee arterial lesions is feasible, safe, and provides favourable one-year clinical results in patients with CLI.

TCT-164

Below-Knee Drug Eluting Stents Have Improved Patency, and Symptoms Compared to Bare Metal Stents: a meta-analysis

Alexandre Benjo[1], Francisco Macedo[1], Emad Aziz[2], Francisco Nascimento[1], Fahad Javed[2], Eyal Herzog[2], Tyrone Collins[3], Christopher White[4]
[1]Columbia University Division of Cardiology, at the Mount Sinai Heart Institute, Miami Beach, FL, [2]Columbia University College of Physicians - St.Lukes-Roosevelt Hospital Center, New York, NY, [3]Ochsner Medical Center, New Orleans, USA, [4]Ochsner Medical Center, New Orleans, Louisiana

Background: Drug eluting stents (DES) have become the standard therapy for coronary interventions, however its benefits on peripheral artery disease are not as clear, particularly in below-knee peripheral arterial disease.
Methods: All randomized controlled trials of drug eluting stents in below-knee peripheral artery disease were sought in PubMed, and Cochrane databases during May 2012. Data was extracted by 3 reviewers and analyzed with RevMan 5.1 software.
Results: Four randomized controlled trials were found. Our analysis demonstrated a clear benefit in patency manifested by a freedom of target lesion revascularization up to four times higher with DES (p=0.001, Figure1) and an improvement of at least one level on the Rutherford classification up to two times higher at 6 to 12 months (p=0.005, Figure 2). There was a non significant trend favoring DES in reducing major amputations (Figure 3) and death incidence was similar.

Figure 1: The freedom of Target Lesion Revascularization is increased in 4 times

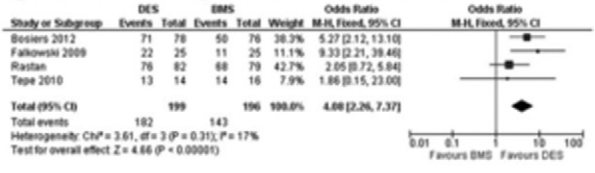


Figure 2: Symptoms improvement – Rutherford classification at least one level improvement

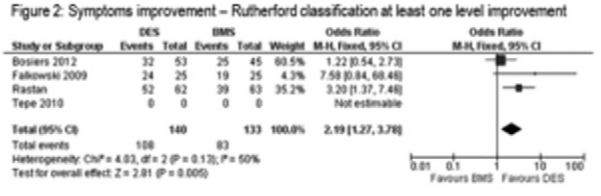
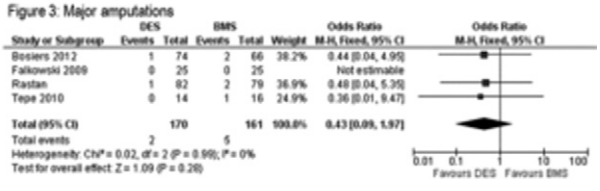


Figure 3: Major amputations



Conclusions: Our meta-analysis shows that DES significantly improves patency and symptoms when compared to BMS for the revascularization of below-knee arterial disease.

TCT-165

Evaluation of Long-term Vascular Responses to Fluorocopolymer coated Self-Expanding low-dose Paclitaxel-eluting Stent in Porcine Ilio-femoral Model

Dongming Hou[1], Barbara Huibregtse[2], William Stoffregen[3], Gordon Kocur[1], Cory Hitzman[1], Elizabeth Stejskal[1], John Heil[1], Keith Dawkins[4]
[1]Boston Scientific Corporation, Maple Grove, MN, [2]Boston Scientific Corporation, Natick, MA, [3]Boston Scientific Corporation, Plymouth, MN, [4]Boston Scientific Corporation, Marlborough, MA

Background: Peripheral interventional therapy to treat occlusive disease for patients with symptomatic claudication is considered standard clinical practice. The present study

POSTERS